K121243

510(k) SUMMARY

MAY 0 3 2013

1. Submitter Information

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Date Prepared: March 30, 2012

2. Device Information

Trade Name: MD-1000A/P Ultrasonic Biometer for Ophthalmology
MD-1000A Ultrasonic Biometer for Ophthalmology
MD-1000P Ultrasonic Pachymeter

Common Name: Ultrasound A/P Scan System for Ophthalmology
Ultrasound A Scan for Ophthalmology
Ultrasound Pachymeter

Classification Name: Ultrasonic Pulsed Echo Imaging System
Diagnostic Ultrasound Transducer

Regulation Number: 892.1560; 892.1570

Product Code: IYO; ITX

3. Predicate Devices

We selected the legally marketed similar products produced by our company as the predicate devices. They have the same intended use and working principle, and are equivalent in structure (including accessories) and technical characteristics. The predicate devices are listed below:

Manufacturer: MEDA Co., Ltd

Device: ODM-1000A/P Biometer
ODM-1000A Ultrasonic A-Biometer
ODM-1000P Ultrasonic Pachymeter

510(k) Number: K063472

4. Device Description

The MD-1000 Series of Ultrasonic Biometer/Pachymeter for Ophthalmology consists of three models of products: the MD-1000A/P Ultrasonic Biometer for Ophthalmology, the MD-1000A Ultrasonic Biometer for Ophthalmology and the MD -1000P Ultrasonic Pachymeter.

The MD-1000A/P Ultrasonic Biometer for Ophthalmology is an ultrasonic measuring instrument based on pulse reflection. The MD-1000A/P contains two function units: A Mode Eye Axis Biometric Parameter Measuring Unit (A Biometer) and Corneal Thickness Measuring Unit (Pachymeter).

The A Biometer:

The A Biometer consists of a 10MHz A-Probe (probe model: Prb1000A/10-C) and an axis biometric parameter measuring unit. The axis is usually divided into three segments: anterior chamber, lens and vitreous body. Since the tissue within the eye varies in different areas, the acoustic velocity through these areas is also different. The summation of these three segments (ACD + LENS + VITR) provides the axial length (AL). Based on the interface reflections of the three different tissues, the ultrasonic A-biometry measures the transmitting time of ultrasound through each tissue and calculates the length of each segment to finally get the axial length.

The Pachymeter:

The Pachymeter consists of a 20MHz P-Probe (probe model: Prb1000P) and the measuring unit. It is on the basis of the measurement of the time interval between the anterior and posterior interface reflection waves of cornea to get the corneal thickness (CT).

The MD-1000 Series has a built-in Thermal Printer, used to print out patient information, A-Scan measuring waveform, IOL calculating parameter and result as well as corneal thickness measuring result and corneal thickness distribution map.

The built-in memory of the MD-1000 Series can store up to180 patients' records. After examination, it can be connected with a computer to upload the stored measuring data and information, thus realizing mass storage.

5. Intended Use

The MD-1000A/P is used for ophthalmology to measure axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and corneal thickness (CT).

The MD-1000A is used for ophthalmology to measure axial length (AL), anterior chamber depth (ACD) and lens thickness (LT).

The MD-1000P is used for ophthalmology to measure corneal thickness (CT).

The device should be operated by trained doctors. It should be used cautiously on babies or patients without independent behavior abilities. It is prohibited to use the device on patients with eye trauma, inflammation or infection.

6. Technological characteristics

a) Safety

The electrical, mechanical, environmental safety testing was performed according to standard IEC60601-1: 2005, Deviations USA/Canada to IEC 60601-1: 2005 and IEC 60601-2-37: 2007.

The EMC testing was conducted in accordance with standard IEC 60601-1-2: 2007. The safety standards performed by the MD-1000 Series are identical with those of the predicate product.

b) Characteristics

A Biometer:
Ultrasonic frequency: 10MHz;
Display resolution: 0.01mm;
Adjustable gain scope: 0~50dB;
Measuring scope (AL): 15 mm~40mm;
Measuring accuracy: Error≤±0.05mm;
Measuring Parameter: ACD, LENS, VITR and AL;
Measuring mode: automatic mode or manual mode can be selectable. Automatic mode for Normal, Cataract and Aphakic mode;
Measuring method: contact and immersion, can be selectable;
IOL calculation: SRK/T, SRK-II, BINK-II, HOLLADAY, HOFFER-Q, HAIGIS.

Pachymeter:
Ultrasonic frequency: 20MHz;
Display resolution: 1μm;
Measuring scope: 0.23mm~1.2mm;
Measuring accuracy: Error≤±5μm.

The MD-1000 Series has similar performance characteristics, controls and indicators, and specifications as its predicate device. It incorporates the same operational principles and technology as the ODM-1000 Series.

The main differences between the MD-1000 Series and its predicate device are: they use different monitors, housing, AC-DC adapters and have different specifications of A-Probe. The details are listed below:

Model / Accessory	Subject Device MD-1000 series (MD-1000A/P, MD-1000A, MD-1000P)	Predicate Device ODM-1000 series (ODM -1000A/P, ODM -1000A, ODM -1000P)
General Safety and Effectiveness	Measuring Range (AL): 15~40mm Measuring Accuracy (AL): ≤±0.05mm	Measuring Range (AL): 15~39mm Measuring Accuracy (AL): ≤±0.06mm
A-probe	Model: Prb1000A/10-C Transducer Diameter: 4.8 mm Focal Length: 30±3 mm	Model: Prb1000A/10 Transducer Diameter: 4 mm Focal Length: 23±3 mm
Monitor	6.4" True Color TFT LCD (640×480 pixels, 18Bit)	5.1" LCD (320×240 pixels)
Power Adapter	Model: HES49-12040 12V/4A (UL E164433)	Model: MW128RA0703F01 7.5V/3A (UL E145177)
Foot Switch	MD-1000.FS-2 (for MD-1000A/P and MD-1000P) MD-1000.FS-1 (for MD-1000A)	Foot Switch for ODM-1000A/P and ODM-1000P Foot Switch for ODM-1000A

It can be found from the above comparison that the AL measurement range and accuracy of the two devices are a little different.

For the AL measuring accuracy, the sampling frequency of the MD-1000A/P to the ultrasonic echo is 24MHz, but the sampling frequency of the ODM-1000A/P is 12MHz. The improvement of the sampling frequency can improve the precision of time measurement, thus improving the AL measuring accuracy.

For the AL measurement range, the original design specifications of the ODM-1000A/P is 15 ~ 40mm, but in actual test, due to the limitation of the LCD display resolution (320 × 240 pixels), the display range reaches 39mm only; the MD-1000A/P utilizes LCD monitor with the resolution of 640 × 480 pixels, thus satisfying the requirements of 15 ~ 40mm AL measurement range.

The ODM-1000 Series uses a 5.1" LCD monitor and membrane keyboard. The MD-1000 Series uses a 6.4" True Color TFT LCD monitor and touch screen. The Safety Test Report showed that it met the requirements of IEC 60601-1 and did not affect the safety of the MD-1000 Series.

The Prb1000A/10-C configured with the MD-1000A/P uses the transducer of φ4.8mm and Focal Length of 30mm. Although there is difference from the characteristics of the A-Probe configured with the ODM-1000A/P, based on the working principle of ultrasonic distance measurement, it is not required to change algorithm and processing hardware. Its algorithm is the same with that of the ODM-1000A/P; and for the processing hardware, except that the sampling frequency increases to 24MHz for the purpose of improving measuring accuracy, the structure of the hardware is not changed. The PEMS Validation Report, Acoustic Output Test Report and Biological Evaluation Test Report proved that, the changes of the A-Probe size and focal length did not affect the safety and AL measuring accuracy.

The MD-1000 Series and ODM-1000 Series use different power adapters and foot switches, but both of them meet the requirements of IEC 60601-1.

While there are some differences between the MD-1000 Series and its predicate device, they do not affect safety or effectiveness.

7. Brief Discussion of Non-clinical Tests

The safety tests based on FDA-recognized standards were conducted by TÜV SÜD Laboratories, and all results comply with the requirements of relevant standards.

The software and essential performance have passed verification and validation, and the results comply with the requirements.

8. Brief Discussion of Clinical Evaluation and Validation

The clinical data of the MD-1000A/P Ultrasonic Biometer for Ophthalmology have been collected and evaluated according to 93/42/EEC MEDDEV. 2.7.1 Rev.3.

The medical literature related to measuring accuracy and scope mainly comes from the Journal of Research in Medical Sciences, J Cataract Refract Surg, Int Ophthalmol and etc.

As part of the product design validation, we have entrusted a hospital to make clinical effectiveness validation. Below is a summary of the details about the clinical validation study:

a) 107 subjects were selected to implement axial length measurement or corneal thickness measurement, among which 60 eyes were for corneal thickness measurement and 47 eyes were for axial length measurement. The age and sex of subjects were not limited and all subjects participated in the clinical tests voluntarily.

b) The MD-1000A/P and similar product (NIDEX-US-500) were used repeatedly to measure corneal thickness of the same eye. One measurement was taken per eye with the two products respectively and a total of 60 subjects (eyes) were measured.

The axial length measurements were conducted in the same way, a total of 47 subjects (eyes) were measured.

c) The Bland-Altman statistical method was used to process the measuring data and assess the agreement of the measurements by the two devices. Take 95% as the limit of agreement.

The statistical processing to the clinical test data showed that there is acceptable agreement for the test results of corneal thickness and axial length between the MD-1000A/P and its similar product; therefore, the MD-1000A/P can satisfy the requirements of the clinical applications.

The clinical test results showed that the MD-1000A/P met the requirements of the intended clinical applications.

No adverse effect was found during the collection and evaluation of clinical data and clinical validation.

The clinical test prompted that the device should be used cautiously on patients without independent behavior abilities or who are highly sensitive to contacting measurements, whose ineffective cooperation may result in inaccurate measurements.

9. Conclusions

The results of non-clinical tests as well as clinical evaluation and validation demonstrate that the MD-1000A/P Ultrasonic Biometer for Ophthalmology, the MD-1000A Ultrasonic Biometer for Ophthalmology and the MD-1000P Ultrasonic Pachymeter are equivalent in safety, effectiveness and performance to the legally marketed predicate devices.

10. MEDA CO., LTD will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

May 3, 2013

MEDA Co. Ltd.
% Mr. Kai Chen
U.S. Designated Agent
Medtech International, Inc.
13505 Broadfield Drive
Potomac, MD 20854

Re: K121243
Trade/Device Name: MD-1000 Series Ultrasonic Biometer for Ophthalmology
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: April 19, 2013
Received: April 29, 2013

Dear Mr. Chen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Opthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121243

Device Name: MD-1000A/P Ultrasonic Biometer for Ophthalmology

MD-1000A Ultrasonic Biometer for Ophthalmology

MD-1000P Ultrasonic Pachymeter

Indications for Use:

The MD-1000A/P is used for ophthalmology to measure axial length (AL), anterior chamber depth (ACD), lens thickness (LT), and corneal thickness (CT).

The MD-1000A is used for ophthalmology to measure axial length (AL), anterior chamber depth (ACD) and lens thickness (LT).

The MD-1000P is used for ophthalmology to measure corneal thickness (CT).

The device should be operated by trained doctors. It should be used cautiously to patients without independent behavior abilities. Cornea trauma or inflammation patients are prohibited to use the device.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K121243

Diagnostic Ultrasound Indications for Use Format

System: MD-1000A/P&MD-1000A

Transducer: Prb1000A/10-C A-Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (A-mode)
Ophthalmic	Ophthalmic							P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Bladder)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number: K121243

System: MD-1000A/P&MD-1000P

Transducer: Prb1000P P-Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (A-mode)
Ophthalmic	Ophthalmic							P
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Bladder)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

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(Division Sign-Off)

Division of Ophthalmic and Ear, Nose, and Throat Devices

510(k) Number: K121243